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Application Number	10/017,697		
	Filing Date	December 7, 2001	
	First Named Inventor	Joyce B. SANTOS	
	Group Art Unit	1615	
	Examiner Name	Blessing M. Fubara	
Total Number of Pages in This Submission	24	Attorney Docket Number	1278-004 (DIZ-1)

ENCLOSURES (check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input checked="" type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Express Mail Label No. EV318225603 US, PTO/SB/17(1p.), Appeal Brief (21pp.), Return Mailroom Postcard.
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Date	March 10, 2005	

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Typed or printed name	Andrea Corliss		
Signature		Date	March 10, 2005

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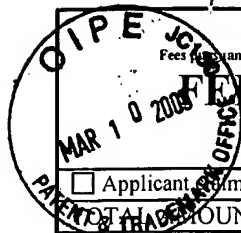
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Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL **For FY 2005**

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT \$500.00

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METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-0289 Deposit Account Name: Wall Mariama & Bilinski LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180
Total Claims		
- 20 or HP =	x	=
HP = highest paid number of total claims paid for, if greater than 20		
Indep. Claims		
- 3 or HP =	x	=
HP = highest number of independent claims paid for, if greater than 3		

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a) (1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/ 50 =	(round up to a whole number) x	=	

4. OTHER FEES - APPEAL BRIEF

Non-English Specification, \$130 fee (no small entity discount)	Fees Paid (\$)
Other:	500.00

SUBMITTED BY

Signature	Thomas T. Aquilla	Registration No. 43,473 (Attorney/Agent)	Telephone 315-425-9000
Name (Print/Type)	Thomas T. Aquilla	Date	March 10, 2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT CASE NAME/NO. 1278_004 (DIZ-1)
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By: _____

Andrea L. Corliss

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Santos *et al.*

Serial No: 10/017,697

Filing Date: 12/07/2001

Title: TASTE MASKED AQUEOUS
LIQUID PHARMACEUTICAL
COMPOSITION

Group Art Unit: 1615

Examiner: Blessing M. Fubara

APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

BRIEF ON APPEAL

This Brief supports the appeal to the Board of Patent Appeals and Interferences from the Final Rejection dated September 10, 2004, in the above-captioned application. Appellant filed a Notice of Appeal on January 10, 2005, and now submits this Brief in compliance with 37 C.F.R. § 1.192.

Pursuant to 37 C.F.R. § 1.192, the two-month period for filing an Appeal Brief tolls from the date of filing the Notice of Appeal, *i.e.*, January 10, 2005. This Appeal Brief is timely filed within the two-month period, which extends until March 10, 2005.

1. REAL PARTY IN INTEREST

The real party in interest is Unilab PharmaTech, Ltd., a Hong Kong limited company. An assignment of the invention claimed in this application from the Appellant to Unilab PharmaTech, Ltd. is recorded in the U.S. Patent and Trademark microfilm records at Reel 012632, Frame 0027. Accordingly, the real party in interest is Unilab PharmaTech, Ltd.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant, Appellant's legal representative, or assignee, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1-46 are pending in the application; claims 1-20, 22-24, 26, 28-33, and 43-46 stand finally rejected.

Claims 35-42 stand allowed.

Claims 21, 25, 27 and 34 stand objected to as depending from a rejected base claim, but the Examiner indicated that claims 21, 25, 27 and 34 also would be allowable if written in independent form, including all of the limitations of the base claim and any intervening claims.

Claims 1-20, 22-24, 26, 28-33, and 43-46 were rejected in the Final Office Action dated September 10, 2004. The pending claims that are the subject of this Appeal are set forth in the attached Claims Appendix.

4. STATUS OF AMENDMENTS

Appellant filed an Amendment After Final Rejection on December 10, 2004, amending independent claims 1 and 43, to add an express limitation requiring the claimed pharmaceutical liquid composition to have a substantially non-bitter taste. Appellant maintains that Entry of the Amendment After Final Rejection quite clearly would overcome all of the outstanding rejections over the prior art of record, particularly since the only reference relied upon to support the rejection is White (US 5,431,916), in which

all of the disclosed compositions have a bitter taste. See White at Column 3, line 21-24 (“An essential component of the present compositions is a tri-ester. Tri-esters are generally clear, viscous liquids with a bitter taste and low toxicity.”). See also Declaration of Dr. Kennie U. Dee, Ph.D., at paragraphs 13-15 and 19-20, and Exhibit 2.

However, the Examiner’s Advisory Action, dated December 29, 2004, states that the proposed Amendment After Final Rejection will not be entered, because it is deemed not to place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Appellant respectfully disagrees, and points out that, in fact, entry of the Amendment After Final Rejection would put all of the pending claims in condition for allowance.

Pursuant to 37 C.F.R. § 41.33(a), the Examiner may enter an Amendment filed after final action, but prior to the date of filing an appeal brief, that places the application in condition for allowance. Further, MPEP § 1207 states that “If, after appeal has been taken, a paper is presented which on its face clearly places the application in condition for allowance, such paper should be entered and a Notice of Allowability form PTOL-37 promptly sent to applicant.”

Appellant respectfully submits that the Amendment After Final Rejection, filed on December 10, 2004, *on its face* clearly places the entire application in condition for allowance, and therefore should be entered and a Notice of Allowance promptly issued. Appellant therefore respectfully requests that this Board reverse the Examiner’s refusal to enter the amendment, and order entry and consideration of the Amendment After Final Rejection.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides a taste-masked oral liquid composition comprising a therapeutically effective amount of at least one bitter-tasting drug. The drug is dissolved or dispersed in an aqueous taste-masking excipient base, comprising a high molecular weight polyethylene glycol, and a polyvinyl pyrrolidone and/or copolyvidone. The taste-masked liquid composition has substantially reduced bitter taste and aftertaste.

Appellant’s invention addresses the problem of the unpleasant taste of a drug in a liquid format, where the liquid composition is a syrup, a ready-to-use suspension, or

extemporaneously prepared liquid syrup or suspension such as, for example, dry powder for reconstitution with water, liquid concentrate for dilution, dispersible tablet or capsule. Specification at page 3, lines 14-17. The taste-masked liquid composition has substantially reduced bitter taste and aftertaste. Specification at page 3, line 3.

6. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-4, 7-8, 10-11, 13, 15-19, 22-24, 26, 28-33 and 43-46 stand finally rejected under 35 U.S.C. 102(b) as being anticipated by White (US 5,431,916).

2. Claims 5-6, 9, 12, 14 and 20 stand finally rejected under 35 U.S.C. 103(a) as being obvious over White (US 5,431,916).

7. ARGUMENTS

(7.1)

**White Does Not Disclose Each And Every Element of
Appellant's Independent Claims 1 and 43**

Claims 1-4, 7-8, 10-11, 13, 15-19, 22-24, 26, 28-33 and 43-46 stand rejected under 35 U.S.C. 102(b) as being anticipated by White (US 5,431,916). Appellant respectfully requests that this Board reverse the rejection.

The Examiner maintains the final rejection on grounds that:

1) the open "comprising" language of the rejected claims does not exclude tri-esters;

2) the composition of White includes a bitter drug, polyethylene glycol and polyvinyl pyrrolidone, which is alleged to meet the limitations of rejected claim 1;

3) therefore, the Examiner concludes that the composition of White must necessarily have properties identical to the properties of the claimed composition, and therefore White's composition must also be taste-masked and thus non-bitter.

Appellant respectfully disagrees with the Examiner's above reasoning, and respectfully points out the errors in the rejection and the reasons why the rejected claims are patentable over the prior art.

First, it is noted that 35 U.S.C § 112, paragraph 2 of the Patent Act provides that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Furthermore, under 35 U.S.C § 112, paragraph 6 of the Patent Act, applicants may describe and claim their inventions in terms of functional features. Certainly, there is no legal requirement that a composition of matter be claimed strictly in terms of its ingredient compounds.

In order to avoid rejection for anticipation, it is only necessary to show that a claim contains at least one element not disclosed in a single prior art reference. Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in prior pleaded art, there is no anticipation. Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628 (Fed. Cir. 1987). The fact that Appellant's claims use open language in the preamble is not particularly relevant; the issue is whether the prior art relied upon by the Examiner discloses an invention having all of the features of Appellant's claims. Therefore, even if a claim recites numerous elements that are present in a single prior art reference, a claim cannot be rejected for anticipation over a single prior art reference that does not disclose each and every element of the claim.

Appellant's independent claim 1 recites, *inter alia*, a **taste-masked liquid** pharmaceutical composition, and original independent claim 43 recites, *inter alia*, a method for preparing a **taste-masked liquid** pharmaceutical composition. Both claims 1 and 43 further require that a **final form of said taste-masked pharmaceutical composition administered to a patient is a liquid.**

White does not disclose any **taste-masked liquid** pharmaceutical composition or a method for preparing it. See White and Declaration of Dr. Kennie U. Dee, Ph.D., particularly at paragraphs 11 and 18. Rather, White discloses the use of a tri-ester and polyvinyl pyrrolidone (PVP), and optionally polyethylene glycol (PEG), as solvent for

pharmaceutical drugs, which are to be encapsulated into soft gelatin capsules. White discloses that the bitter taste and aroma of a bitter drug can be overcome by encapsulation within a soft gelatin capsule, which prevents the consumer from tasting the drug, while the soft gelatin capsule is in the mouth, because the bitter drug does not contact the tongue. See White at Column 1, lines 26-33. White also teaches that tri-esters are bitter. See White at Column 1, lines 21-24.

The pharmaceutical compositions disclosed by White are encapsulated and thus clearly are not administered to a patient in liquid form, as required by Appellant's claims. See Declaration of Dr. Kennie U. Dee, Ph.D., at paragraphs 11 and 18. Indeed, White does not disclose a single example of a composition that includes each and every element of Applicant's claim 1 or 43 and is administered in a non-encapsulated, liquid form. More particularly, the Examiner asserts that White's examples I and V are suitable for oral administration, however, neither example I nor example V include any polyethylene glycol (PEG), which is required by Appellant's claims 1 and 43. Thus, White's examples I and V do not anticipate claim 1 or 43. Indeed, all of the examples purported by White to be suitable for oral administration either do not include PEG, or are not administered in liquid form (or both). Thus, White does not disclose any pharmaceutical composition that meets all of the limitations of Appellant's claims 1 or 43, and therefore the reference cannot anticipate claims 1 or 43.

Furthermore, all of the examples disclosed by White are necessarily bitter-tasting compositions, as described by White at Column 3, line 21-24: "An essential component of the present compositions is a tri-ester. Tri-esters are generally clear, viscous liquids with a bitter taste and low toxicity." Further evidence establishing the bitterness of White's compositions, and of tri-esters in liquid pharmaceutical compositions generally, is found in Exhibit 2 of the Declaration of Dr. Kennie U. Dee, Ph.D. (particularly at paragraphs 13-15). Thus, the compositions disclosed by White contain tri-esters and therefore have a **substantially bitter taste** (due at least in part to the presence of the tri-ester), **which is not masked** and therefore is perceptible by a patient. See White at Column 1, lines 21-24, and Declaration of Dr. Kennie U. Dee, Ph.D. (particularly Exhibit

2). However, Appellant's claims 1 and 43 require the composition to be **taste-masked**. Thus, even assuming that White discloses a pharmaceutical composition that is administered to a patient in liquid form, it would nevertheless be a bitter-tasting composition. Therefore, White does not disclose a taste-masked liquid composition as recited in claim 1 or 43, or the taste-masking of any liquid composition whatsoever.

The Examiner asserts that the composition of White is identical to the composition claimed in the present application. However, the Examiner provides absolutely no evidence whatsoever to support the assertion that the compositions are identical, therefore, the rejection is not supported by substantial evidence. It is hereby noted that the Examiner is required to support the rejection with actual evidence, as opposed to mere conclusory statements. See, *e.g.*, In re Zurko, 142 F.3d 1447, 46 USPQ2d 1691 (Fed. Cir., 1998). Further, if the Examiner relies upon the theory of inherency, then the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). It is noted that the Examiner has not provided any reasonable basis in fact and/or technical reasoning to support a rejection for anticipation by inherency.

Appellant, on the other hand, has provided ample evidence showing that the claimed composition is not identical to that of White, and that claims 1 and 43 are distinguished over the prior art. Indeed, Appellant performed blind taste tests, which demonstrate the bitter taste of the prior art compositions and the substantially non-bitter taste of Appellant's claimed compositions. In summary, White's composition is bitter, whereas Appellant's composition is taste-masked and as such, is non-bitter. This difference alone clearly distinguishes the claimed composition from that of the prior art. Other differences between the compositions are described in detail in Appellant's specification and the Declaration of Dr. Kennie U. Dee, Ph.D., already of record.

Accordingly, Appellant respectfully requests that this Board reverse the rejection of claims 1-4, 7-8, 10-11, 13, 15-19, 22-24, 26, 28-33 and 43-46 under 35 USC § 102 as being anticipated by White.

(7.2)

**White Fails to Raise A *Prima Facie* Case of Obviousness
Against Claims 5-6, 9, 12, 14 and 20**

Claims 5-6, 9, 12, 14 and 20 stand rejected under 35 U.S.C. 103(a) as being obvious over White (US 5,431,916). Appellant respectfully requests that this Board reverse the rejection.

It is well established that a rejection under § 103 requires that the Patent Office show a motivation or suggestion to modify (or combine) the references along with a reasonable expectation that the combined references would result in the claimed invention. In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991). “Both the suggestion and the reasonable expectation of success must be founded in the prior art, not the applicant’s disclosure.” Id. Further, the rejection cannot be predicated on the mere identification of individual components in the prior art. “Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.” In re Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000).

It is respectfully submitted that the Examiner has not met the initial burden of setting forth a *prima facie* case of obviousness. First, it is duly noted that, in order to establish a *prima facie* case of obviousness, the Examiner must establish that the prior art provides some teaching, suggestion or motivation to combine or modify the cited references, as described in Appellant’s disclosure, otherwise, the Examiner is using impermissible hindsight to reject the claims. Further, the Examiner must show that one of ordinary skill in the art would have a reasonable expectation of success in making the claimed invention. Secondly, it is noted that the Examiner is required to support the obviousness rejection with actual evidence, as opposed to mere conclusory statements. See In re Zurko, 142 F.3d 1447, 46 USPQ2d 1691 (Fed. Cir., 1998).

There is no teaching in the prior art of record that one of ordinary skill in the art would be motivated to modify White, or would have a reasonable expectation of success in modifying White, as suggested by the Examiner. See Declaration of Dr. Kennie U. Dee, Ph.D. at paragraphs 18-21. Thus, White does not teach or suggest Appellant's invention as recited in claim 1. In improving the taste of a liquid pharmaceutical composition or an extemporaneously prepared liquid pharmaceutical composition for direct oral ingestion, a person of ordinary skill in the art would not use a known bitter excipient. In other words, one does not try to improve the taste of a bitter drug by adding a known bitter ingredient/excipient, such as a tri-ester.

Moreover, White does not even disclose all of the elements of Appellant's claim 1. The arguments above as to the novelty of independent claim 1 are repeated here by reference, rather than repeating them verbatim. In short, White does not teach or suggest a taste-masked liquid pharmaceutical composition, wherein a final form administered to a patient is a liquid having a substantially non-bitter taste.

Appellant's invention addresses the problem of the unpleasant taste of a drug in a liquid format, where the liquid composition is a syrup, a ready-to-use suspension, or extemporaneously prepared liquid syrup or suspension. Specification at page 3, lines 14-17. The taste-masked liquid composition has substantially reduced bitter taste and aftertaste. Specification at page 3, line 3. White's invention, on the other hand, is "a pharmaceutical encapsulated composition" (see, *e.g.*, claims 1-19). Indeed, all of the examples disclosed by White are compositions and methods for manufacture of pharmaceuticals that are encapsulated within soft gelatin capsules, and thus are not administered in liquid form. Thus, White provides a solution to a different problem, which is that of solubility.

Furthermore, White's composition is a solid at room temperature, and a bitter-tasting solid at that. See Declaration of Dr. Kennie U. Dee, Ph.D. (particularly paragraph 13 and Exhibit 2). White provides absolutely no teaching whatsoever regarding a taste-masked liquid pharmaceutical composition or a method for making the same. For example, White teaches that polyethylene glycol may be used to solubilize certain pharmaceutical actives (column 6, lines 41-42), stating that polyethylene glycol may be

employed to facilitate the solubility of actives or modify the viscosity of suspensions (column 7, lines 24-30). However, the reference does not teach the use of polyethylene glycol to create a taste-masking effect in a liquid pharmaceutical composition. Indeed, White does not provide any teaching regarding the taste-masking effect of the embodiments disclosed therein. While brief mention is made of the suitability of the compositions for oral administration, there is absolutely no teaching regarding a taste-masking effect and/or taste acceptability of the preparations. Similarly, White discloses that polyvinyl pyrrolidone is a solubilizing or a suspending agent in combination with the tri-ester, however, the reference provides no teaching that polyvinyl pyrrolidone should be used to create a taste-masking effect in a liquid pharmaceutical composition. Thus, White does not teach or suggest Applicant's invention as recited in claim 1.

Furthermore, there is no evidence of record whatsoever to support the Examiner's repeated assertions that the claimed compositions are identical to the compositions disclosed by White. Therefore, the rejection is not supported by substantial evidence. As discussed above, White does not disclose, teach or suggest a taste-masked liquid pharmaceutical composition that is administered to a patient in liquid form. In short, there is nothing in the prior art that would lead one of ordinary skill to modify White as suggested by the Examiner, and there is no reasonable expectation of success, particularly since White does not even disclose all of the limitations of the present invention. Absent objective evidence of a motivation to modify the reference, and a reasonable expectation of success, the rejection appears to be based on improper hindsight.

Accordingly, Appellant respectfully requests that this Board reverse the rejection of claims 5-6, 9, 12, 14 and 20 as being obvious over White.

8. **CONCLUSION**

In conclusion, Appellant respectfully requests that this Board reverse each of the grounds of rejection maintained by the Examiner.

If there are any other fees due in connection with the filing of this Brief on Appeal, please charge the fees to **Deposit Account No. 50-0289**. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to the Deposit Account.

PATENT CASE NAME/NO. 1278_004 (DIZ-1)
EXPRESS MAIL LABEL NO. EV318225603 US

Respectfully submitted,

Wall Marjama & Bilinski LLP

By: Thomas T. Aquilla
Thomas T. Aquilla
Registration No. 43,473
(607) 256-7330
Wall Marjama & Bilinski LLP
101 S. Salina Street
Suite 400
Syracuse, NY 13202

Dated: 3/10/2005

(A1)

CLAIMS APPENDIX

Claims on Appeal

1. (Previously presented) A taste-masked liquid pharmaceutical composition or extemporaneously prepared liquid pharmaceutical composition, comprising:

at least one unpleasant tasting drug;

polyethylene glycol of molecular weight at least 900, and

polyvinyl pyrrolidone and/or copolyvidone,

wherein a final form of said taste-masked pharmaceutical composition administered to a patient is a liquid.
2. (Original) The method according to Claim 1, wherein said liquid pharmaceutical composition has a pH from about 2.5 to about 8.
3. (Original) The liquid pharmaceutical composition according to Claim 1, wherein the unpleasant drug is an aromatic compound with a hydrophilic group(s) that can form hydrogen bonds such as hydroxyl, carboxylic or amine groups.
4. (Previously presented) The liquid pharmaceutical composition according to Claim 1 wherein the unpleasant drug is present at about 0.02 to about 15 percent by weight.
5. (Original) The liquid pharmaceutical composition according to Claim 1, wherein the amount of polyethylene glycol is from about 0.05 to about 10 weight percent.
6. (Original) The liquid pharmaceutical composition according to Claim 5, wherein the amount of polyethylene glycol is from about 0.1 to about 5 weight percent.
7. (Original) The liquid pharmaceutical composition according to Claim 1, wherein said polyethylene glycol is of molecular weight of from about 2000 to about 8000.

8. (Original) The liquid pharmaceutical composition according to Claim 1, wherein the polyvinyl pyrrolidone and/or copolyvidone is present at about 0.1 to about 30 weight percent.
9. (Original) The liquid pharmaceutical composition according to Claim 8, wherein the polyvinyl pyrrolidone and/or copolyvidone is present at about 1 to about 7 weight percent.
10. (Original) The liquid pharmaceutical compositions according to Claim 1, further comprising a sweetening agent and/or a viscosity building agent.
11. (Original) The liquid pharmaceutical composition according to Claim 10, wherein the said sweetening agent is selected from the group consisting of sugar, invert sugar, glucose, fructose, sorbitol, mannitol, xylitol, a high intensity artificial sweetener, a dipeptide sweetener, and combinations thereof.
12. (Original) The liquid pharmaceutical composition according to Claim 10, wherein said sweetening agent is present at about 30 to about 90 weight percent.
13. (Original) The liquid pharmaceutical composition according to Claim 10, wherein the said viscosity-building agent is selected from the group consisting of glycerin, xanthan gum, carrageenan, tragacanth, guar gum, pectin, carboxymethylcellulose, hydroxypropyl methylcellulose, methylcellulose, microcrystalline cellulose and carboxymethylcellulose blends, and mixtures thereof.
14. (Original) The liquid pharmaceutical composition according to Claim 10, wherein said viscosity building agent is present in an amount from about 0.1 to about 3 weight percent.
15. (Original) The liquid pharmaceutical composition according to Claim 1, wherein said composition is used to treat fever, infection, headache, pain, inflammation, excess mucus or phlegm, coughing, allergies, allergic diseases, nausea, vomiting, and motion sickness.

16. (Original) The liquid pharmaceutical composition according to Claim 15, wherein said unpleasant tasting drug is selected from the group consisting of an analgesic, an anti-inflammatory drug, an antihistamine, a decongestant, anti-infective, a mucolytic, an antitussive, an expectorant, and combinations thereof.
17. (Original) The liquid pharmaceutical composition according to Claim 16, wherein said analgesic or said anti-inflammatory drug is selected from the group consisting of acetaminophen, ibuprofen, naproxen, mefenamic acid, ketoprofen, celecoxib, rofecoxib, and tramadol, and combinations thereof.
18. (Original) The liquid pharmaceutical composition according to Claim 16, wherein said antihistamine is selected from the group consisting of loratadine, descarboethoxyloratadine, diphenhydramine, brompheniramine, chlorpheniramine, terfenadine, cetirizine, and combinations thereof.
19. (Original) The liquid pharmaceutical composition according to Claim 16, wherein said decongestant is selected from phenylpropanolamine, pseudoephedrine, phenylephrine, and combinations thereof.
20. (Original) The liquid pharmaceutical composition according to Claim 16, wherein said anti-infective is selected from amoxicillin, ampicillin, cloxacillin, flucloxacillin, penicillin, cephalixin, and combinations thereof.
21. (Original) The liquid pharmaceutical composition according to Claim 16, wherein said mucolytic is selected from the group consisting of ambroxol, carbocisteine, and bromhexine, and combinations thereof.
22. (Original) The liquid pharmaceutical composition according to Claim 16, wherein said antitussive or said expectorant is selected from the group consisting of caramiphen, dextromethrophan hydrobromide, codeine phosphate, codeine sulfate, guaifenesin, and combinations thereof.
23. (Original) The liquid pharmaceutical composition according to Claim 22, wherein said guaifenesin is present in an amount of about 1 to about 5 weight percent.

24. (Original) The liquid pharmaceutical composition according to Claim 23, further comprising at least one additional drug selected from the group consisting of a bronchodilator, a mucolytic, an antitussive, and combinations thereof.
25. (Original) The liquid pharmaceutical composition according to Claim 24, wherein said bronchodilator is selected from the group consisting of salbutamol, terbutaline, theophylline, and combinations thereof.
26. (Original) The liquid pharmaceutical composition according to Claim 24, wherein said antitussive is selected from the group consisting of caramiphen, dextromethrophan hydrobromide, codeine phosphate, codeine sulfate, and combinations thereof.
27. (Original) The liquid pharmaceutical composition according to Claim 24, wherein said mucolytic is selected from the group consisting of ambroxol, carbocysteine, and bromhexine, and combinations thereof.
28. (Original) The liquid pharmaceutical composition according to Claim 17, wherein said acetaminophen is present in an amount of about 1 to about 10 weight percent.
29. (Original) The liquid pharmaceutical composition according to Claim 28, further comprising at least one additional drug selected from the group consisting of an analgesic, an anti-inflammatory drug, an antihistamine, a decongestant, an antitussive, an expectorant, a mucolytic, and combinations thereof.
30. (Original) The liquid pharmaceutical composition according to Claim 29 wherein said analgesic or said anti-inflammatory agent is selected from the group consisting ibuprofen, naproxen, mefenamic acid, ketoprofen, celecoxib, rofecoxib, tramadol, and combinations thereof.
31. (Original) The liquid pharmaceutical composition according to Claim 29, wherein said antihistamine is selected from the group consisting of loratadine, descarboethoxyloratadine, diphenhydramine, brompheniramine, chlorpheniramine, terfenadine, cetirizine, and combinations thereof.

32. (Original) The liquid pharmaceutical composition according to Claim 29, wherein the decongestant is selected from the group consisting of phenylpropanolamine, pseudoephedrine, phenylephrine, and combinations thereof.
33. (Original) The liquid pharmaceutical composition according to Claim 29, wherein said antitussive or said expectorant is selected from the group consisting of caramiphen, dextromethrophan hydrobromide, codeine phosphate, codeine sulfate, guaifenesin, and combinations thereof.
34. (Original) The liquid pharmaceutical composition according to Claim 29, wherein said mucolytic is selected from the group consisting of ambroxol, carbocisteine, and bromhexine, and combinations thereof.
35. (Original) A liquid pharmaceutical composition comprising:
- 5 g acetaminophen, 0.3 g xanthan gum, 55 g sucrose, 10 g 70% sorbitol solution, 20 g invert sugar, 5 g glycerin, 2.5 to 5 g crospovidone, 0 to 2.5 g polyethylene glycol with an average molecular weight between 1000 to 4000, 0.2 g sodium benzoate, 0.05 g sorbitan monolaurate, 0.2 g edetate disodium, 0.2 g sucralose, 0.13 g saccharin sodium, 0 to 0.006 g FD&C or D&C color, 0.2 to 0.4 g flavor, water to a volume of 100 mL, citric acid-sodium citrate dihydrate to a pH of 5 to 6.
36. (Original) A liquid pharmaceutical composition comprising:
- 10 g acetaminophen, 0.3 g xanthan gum, 54 g sucrose, 10 g 70% sorbitol solution, 20 g invert sugar, 5 g glycerin, 5 to 10 g crospovidone, 0 to about 1 g polyethylene glycol with an average molecular weight between 1000 to 4000, 0.2 g sodium benzoate, 0.05 g sorbitan monolaurate, 0.2 g edetate disodium, 0.4 g sucralose, 0.26 g saccharin sodium, 0 to 0.006 g FD&C or D&C color, 0.2 to 0.4 g flavor, water to a volume of 100 mL, citric acid-sodium citrate dihydrate to a pH of 5 to 6.
37. (Original) A liquid pharmaceutical composition comprising:

2 to 4 g guaifenesin, 51 g sucrose, 30 g 70% sorbitol solution, 7.5 g glycerin, 2.5 g to 5 g povidone, 0 to 1.5 g polyethylene glycol with an average molecular weight between 1000 to 4000, 0.2 g sodium benzoate, 0.1 g sucralose, from about 0.2 to about 0.4 g flavor, water to a volume of 100 mL, citric acid to a pH of 3 to 4.

38. (Original) A liquid pharmaceutical composition comprising :

0.3 g dextromethorphan hydrobromide, 60 g sucrose, 20 g invert sugar, 2.5 g to 5 g povidone, from about 0 to 1 g polyethylene glycol with an average molecular weight between 1000 to 6000, 0.2 g sodium benzoate, 0.2 g sucralose. 0.13 g saccharin sodium, 0.2 to about 0.4 g flavor, water to a volume of 100 mL, citric acid-sodium citrate dihydrate to a pH of 4.5 to 5.5.

39. (Original) A liquid pharmaceutical composition comprising :

0.3 g diphenhydramine hydrochloride, 40 g 70% sorbitol solution, 30 g glycerin, 2.5 g to 5 g povidone, 0 to 2.25 g polyethylene glycol with an average molecular weight between 1000 to 8000, 0.2 g sodium benzoate, 0.2 g sucralose. 0.13 g saccharin sodium, 0.2 to 0.4 g flavor, water to a volume of 100 mL, citric acid-sodium citrate dihydrate to a pH of 4.5 to 5.5.

40. (Original) A liquid pharmaceutical composition comprising :

0.08 g brompheniramine maleate, 40 g 70% sorbitol solution, 30 g glycerin, 2.5 g to 5 g povidone, 0 to 2.25 g polyethylene glycol with an average molecular weight between 1000 to 8000, 0.2 g sodium benzoate, 0.2 g sucralose. 0.13 g saccharin sodium, 0.2 to 0.4 g flavor, water to a volume of 100 mL, citric acid-sodium citrate dihydrate to a pH of 3 to 4.

41. (Original) A ready-to-use powder or granules for reconstitution wherein after reconstitution to 100 mL with water, the liquid pharmaceutical composition comprises:

3.25 to 13 g amoxicillin trihydrate, 45 g sucrose, 0.06 g sorbitan monolaurate, 0.5 to 2.5 g povidone and/or copolyvidone, 0.1 to about 0.5 g polyethylene glycol with an average molecular weight between 1000 to 8000, 0.10 g methylparaben, 0.02 propylparaben, 0 to 0.004 g FD&C or D&C color, 0.20 to 1 g flavor, 1.2 g precipitated silica, and sodium citrate to pH 4-6.

42. (Previously presented) A ready-to-use powder or granules for reconstitution wherein after reconstitution to 100 mL with water, the liquid pharmaceutical composition comprises:

2 to 10 g cloxacillin sodium, 45 g sucrose, 0.06 g sorbitan monolaurate, 0.5 to 2.5 g povidone and/or copolyvidone, 0.1 to about 0.5 g polyethylene glycol with an average molecular weight between 1000 to 8000, 0.10 g methylparaben, 0.02 propylparaben, 0 to 0.004 g FD&C or D&C color, 0.20 to 1 g flavor, 1.2 g precipitated silica, and sodium citrate to pH 4-6.

43. (Previously presented) A method for preparing a taste-masked liquid pharmaceutical composition, comprising combining:

at least one unpleasant-tasting drug;

polyethylene glycol with a molecular weight of at least 900;

polyvinyl pyrrolidone and/or a copolyvidone; and

an aqueous liquid excipient base,

resulting in a taste-masked pharmaceutical composition that is administered in liquid form.

44. (Original) The method according to Claim 43, wherein said polyethylene glycol has an average molecular weight of from about 2000 to about 8000.

45. (Original) The method according to Claim 43, wherein said polyethylene glycol has an average molecular weight of from about 4000 to about 6000.

46. (Original) The method according to Claim 43, wherein said liquid pharmaceutical composition further comprises one or more additives selected from the group consisting of sweetening agents, flavors, colorants, antioxidants, chelating agents, viscosity-building agents, surfactants, pH modifiers, bulking agents, acidifiers, cosolvents, anticaking agents, and mixtures thereof.

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EVIDENCE APPENDIX

Copies of any evidence entered and relied upon in the appeal.

NONE

(A3)

RELATED PROCEEDINGS APPENDIX

Copies of decisions rendered by a court or the Board in any proceeding identified in the related appeals and interferences section.

NONE